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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,701	11/18/2003	Scott P. Fulton	G0744.70043US01	5425

31904 7590 03/26/2007

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,701	FULTON ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on December 26, 2006 have been received and entered into the case. Claims 1 – 19 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for producing a buffer, however are rendered vague and indefinite for reciting "pumping" because it is unclear if the method requires the solutions be pumped together, from a particular place, to a particular place, or if it simply requires the solution to be blended in a pumping motion. Since the claims recite "pumping and blending" it is unclear how the terms differentiate from one another in the context of the claims.

Claims 3 – 4 and 6 – 9 are rendered vague and indefinite because the claims appear to be drawn to a separate method of producing products, which do not further limit the method for producing a solution. Moreover, these claims appear to be drawn to other, non-related method claims.

Claim 4 is rendered indefinite because it depends on itself.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holum, Voet, Liebrecht, Moran, Ilium and/or Fulton.

Applicant claims a method of producing pH buffered solutions comprising the pumping and blending of water, buffering acids and bases and other required ingredients in solution at a controlled manner and the buffering of acids and bases in a solution. The buffers produced are used for processing a biopharmaceutical, specifically human serum albumin, or product

feedstock and are produced continuously. The feedstream is transgenic, produces milk, or is derived from a cell culture broth. The entire process is sterile.

Holum teaches a method of producing a buffer using acids and bases to obtain a specific pH by adding acids and bases to water, mixing and recording the pH (see pg. 207-208).

Voet teaches buffer solutions, calculating a desired pH using the Henderson-Hasselbalch equation, the buffering effects of acids and bases based on the nature of acid-base reactions, and production of buffers by adding acid and/or base to water (see p.35-38). Further, they disclose the addition of an acid to water to obtain a desired pH and specifically show points at which a solution can function effectively as a buffer (see Fig. 2-9). Although the reference only briefly teaches a method of producing a buffer, one of ordinary skill in the art would know how to prepare a buffer from mixing water either by hand or with a stir bar and how to buffer a solution by adding acids and/or bases to the solution to obtain a desired pH. In support, Wikipedia encyclopedia (http:llen.wikipedia.or,qlwikilBuffer solution). Wikipedia provides a complete teaching of buffer solutions, calculating a desired pH using the Henderson-Hasselbalch equation, the buffering effects of acids and bases, tips on preparing an ideal buffer, i.e, one with a desired pH, common buffers used in Biology, such as TAPS, TRIS, HEPES, MOPS, MES etc. all commonly used buffers in biological sciences. Wikipedia also teaches how to prepare buffer solutions comprising the steps of mixing acids and bases and water to achieve specific pH's.

Liebrecht et al teach the production of a formulation, which comprises the blending of water with other necessary ingredients and adjusting the pH of formulation with an acid to obtain a desired pH (see columns 2, lines 44-56, columns 3-4 lines 65-4).

Moran teaches the production of low and high pH buffered solutions comprising mixing water and acids and/or bases and additional ingredients to achieve a solution with a desired pH (see abstract, summary of invention and column 4, lines 35-65).

Ilium teaches the preparation of buffered solutions comprising mixing sodium phosphate and water to obtain the desired pH. Insulin solutions were then prepared in the phosphate buffer (see column 6, lines 30-39).

Fulton teaches the processing of a feedstream, specifically, transgenic milk and/or transgenic cell cultures by applying the samples to an affinity column to obtain human serum albumin. Fulton also suggests using continuous chromatography, specifically simulated moving bed chromatography (see p.5, section 0056) to purify hSA from a transgenic source. Fulton further discloses the necessary use of buffers at specific pH's throughout the purification process and also discloses a need to treat the transgenic milk with an acid, which in turn lowers pH and removes the casein present in the milk. Although Fulton does not specifically teach the a method of producing a buffer, a method of buffering a solution, i.e. milk with an acid, hSA with an acid or base (0053), salt, wash and elution buffers are adjusted by adding acid and/or salt (0051 and 0053), is taught and those buffers are further used in the hSA production process.

None of the references teach the method wherein the components are "pumped" as claimed. However, each of the references clearly evidence that the combining, mixing and/or blending of water with acids and bases are a known an effective manner in which to obtain a pH buffered solution. Thus, at the time of the claimed invention, it would have been well within the purview to also "pump" the ingredients together as a matter of routine experimentation, and as guided by the prior art. Moreover, at the time of the claimed invention, one of ordinary skill in

the art would have been motivated by the prior art to pump, or combine, mix, blend water together with acids, bases and other components with a reasonable expectation for successfully producing a buffered solution.

Regarding the steps of the further processing the solutions (i.e. the steps of further processing a biopharmaceutical or product feedstream), these claims have been interpreted as intended use type limitations of the product obtained by the claimed process. Moreover, while some of the cited references do not teach that their compositions can be used to further process biopharmaceuticals or product feedstreams, the intended use of the claimed end solution does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore the claims are rejected.

Response to Arguments

Applicant argues that the references do not teach "pumping" the ingredients together.

However, as indicated in the rejection above, it would have been well within the purview of one in the art to pump the ingredients together as an alternative to mixing, blending, combining and/or agitating as disclosed in the prior art.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RUTH A. DAVIS
PATENT EXAMINER